

Remarks

Applicant respectfully traverses the restriction requirement.

Applicant's claims are directed to a multi-layer oral dosage form. The oral dosage form includes:

- (a) a matrix core comprising a therapeutical effective amount of a first drug, wherein the matrix core allows sustained release of the first drug;
- (b) a first layer, which is in contact with said matrix core, comprising a first portion of a pharmaceutically effective amount of a second drug, wherein the first layer allows sustained release of the second drug; and
- (c) a second layer, which is also in contact with said matrix core, comprising a second portion of the second drug, wherein the second layer allows immediate release of the second drug.

The Examiner states that:

The inventions of Groups I-VIII do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: the common technical feature in all groups is a multilayer oral dosage form with an immediate release portion and a sustained release portion.

Applicant respectfully disagrees with the Office Action's characterization of Applicant's invention. Applicant submits that the "common technical feature" in all groups is a multilayer oral dosage form with (a) "a matrix core ... [allowing] sustained release of the first drug"; (b) "a first layer, which is in contact with said matrix core, ... wherein the first layer allows sustained release of the second drug"; and (c) "a second layer, which is also in contact with said matrix core, ... wherein the second layer allows immediate release of the second drug."

The Office Action further states that “Plachetka teaches a multilayerd oral dosage form with an intermediate release portion and a sustained release portion.” Applicant submits that Plachetka appears to teach an intermediate release portion and a sustained release portion. Applicant, however, contends that Plachetka does not appear to teach or suggest a multilayer oral dosage form with (a) a matrix core allowing sustained release of the first drug; (b) a first layer, which is in contact with said matrix core, wherein the first layer allows sustained release of the second drug; and (c) a second layer, which is also in contact with said matrix core, wherein the second layer allows immediate release of the second drug. For example, referring to Figures 1-3 of Plachetka, it can be seen that the layers of Plachetka are formed in expanding circles around a core. In contrast, referring to Applicant’s Figure 1, the layers are disposed in a linear fashion such that the first and second layers contact the matrix core. As such, Applicant submits that Plachetka does not appear to teach or suggest the “special technical features” of Applicant’s claims. Applicant respectfully requests that the Examiner reconsider the restriction of Applicant’s claims in view of the above discussion.

If Applicant’s arguments are not persuasive, Applicant hereby elects the claims of Group I, namely claims 1, 28 and 30.

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10/542,983

Applicant respectfully requests a two-month extension of time. A fee authorization form is enclosed to cover the fee for the extension of time. If any further extension of time is required, Applicant hereby requests the appropriate extension of time. If any fees are inadvertently omitted or if any additional fees are required or have been overpaid, please appropriately charge or credit those fees to Meyertons, Hood, Kivlin, Kowert & Goetzel, P.C. Deposit Account Number 50-1505/6165-10702/EBM.

Respectfully submitted,

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